

EU Declaration of Conformity

Legal Manufacturer: Address:	i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea
SRN (Single Registration Number):	KR-MF-000009173
EU Authorised Representative: Address:	Medical Technology Promedt Consulting GmbH Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
EAR SRN (Single Registration Number):	DE-AR-000000085

Product Name:	alphacheck CareSens Dual
Model No:	Refer to Appendix 1
Basic UDI-DI&EMDN code:	Refer to Appendix 1
Start of CE Marking:	2023-11-10

This Declaration of Conformity is issued under the sole responsibility of i-SENS, Inc.
We hereby declare that the above-mentioned product is in conformity with all applicable provision of the following legislative acts:

- In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
- Radio Equipment Directive 2014/53/EU
- Restriction of Hazardous Substances Directive 2011/65/EU

All supporting documentation is retained under the premises of the manufacturer.

In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

Classification:	Class C
Notified Body:	TÜV SÜD Product Service GmbH (NB no. 0123)
EU Certificate:	V74 090700 0038 Rev.00
Conformity Assessment Procedure:	Annex IX of the Regulation (EU) 2017/746

Radio Equipment Directive 2014/53/EU

Harmonised Standards:	EN 300 328 V2.2.2
Conformity Route:	Module A

Restriction of Hazardous Substances Directive 2011/65/EU

Harmonised Standards:	EN IEC 63000:2018
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Signature:	Signed for and on behalf of i-SENS  Joon Ho Jung RA Team Leader & PRRC
Place, Date of issue:	Seoul, 2023-11-10

Declaration of Conformity, Appendix 1
List of Products

Product	Model no.	EMDN code	Basic UDI-DI
alphacheck CareSens Dual Blood Glucose and β -Ketone Monitoring System	-	DIABETES MONITORING: W02010601	8806712BGMS/BKMS001YX
alphacheck CareSens Dual Blood Glucose and β -Ketone Meter	GM01HAC	VARIOUS DIABETES MONITORING INSTRUMENTS - OTHER: W020106019099	8806712BGM/BKMME001LZ
alphacheck CareSens PRO Blood Glucose Test Strips	GSB02	GLUCOSE TEST STRIPS: W0101060101	8806712BGMTS00239
alphacheck KetoSens Blood β -Ketone Test Strips	KSD03	KETONE TEST STRIPS (B HYDROXYBUTYRATE TEST STRIPS): W0101060110	8806712BKMTS0015B
alphacheck CareSens PRO Glucose Control Solutions	GCB02	BLOOD TEST STRIPS CONTROLS: W010106010801	8806712BGMCS001V9
alphacheck KetoSens β -Ketone Control Solutions	KCD03	BLOOD TEST STRIPS CONTROLS W010106010801	8806712BKMCS001XD